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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-----------------------|----------------------------|-------------------------|-----------------------|------------------|--|
| 10/596,489 | 03/20/2007 | Kamaluddin Abdur-Rashid | 14696-13 | 7292 | |
| 1059 BERESKIN A) | 7590 11/30/2007 ND PARR | | EXAMINER | | |
| 40 KING STREET WEST | | | NWAONICHA, CHUKWUMA O | | |
| BOX 401 TORONTO, O | N M5H 3Y2 | | ART UNIT | PAPER NUMBER | |
| CANADA | | | 1621 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | A | pplication No. | Applicant(s) | | | | |
|---|--|--|--|--------------------------|--|--|--|
| Office Action Summary | | 0/596,489 | | ABDUR-RASHID, KAMALUDDIN | | | |
| | | xaminer | Art Unit | | | | |
| | | hukwuma O. Nwaonicha | 1621 | | | | |
| The MAILING DATE of this com Period for Reply | munication appear | s on the cover sheet wit | h the correspondence a | ddress | | | |
| A SHORTENED STATUTORY PERIOD WHICHEVER IS LONGER, FROM THE Extensions of time may be available under the provafter SIX (6) MONTHS from the mailing date of this If NO period for reply is specified above, the maxime Failure to reply within the set or extended period for Any reply received by the Office later than three more earned patent term adjustment. See 37 CFR 1.704 | IE MAILING DATE isions of 37 CFR 1.136(a) communication. um statutory period will appropriately will, by statute, caughts after the mailing date | OF THIS COMMUNIC In no event, however, may a re oply and will expire SIX (6) MONT se the application to become ABA | CATION. Exply be timely filed ITHS from the mailing date of this of the control | | | | |
| Status | | | | | | | |
| 1) Responsive to communication(s | s) filed on 20 Marc | h 2007. | | | | | |
| 2a) ☐ This action is FINAL . | . · · · · · · · · · · · · · · · · · · <u> </u> | | | | | | |
| 3) Since this application is in cond | , | | | | | | |
| closed in accordance with the p | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | | |
| 4)⊠ Claim(s) <u>1-56</u> is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) <u>54-56</u> | 4a) Of the above claim(s) <u>54-56</u> is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6)⊠ Claim(s) <u>1-53</u> is/are rejected. | ☑ Claim(s) <u>1-53</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected t |)☐ Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to re | estriction and/or el | ection requirement. | | | | | |
| Application Papers | | | | | | | |
| 9)☐ The specification is objected to b | y the Examiner. | | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | |
| Applicant may not request that any | objection to the drav | wing(s) be held in abeyand | ce. See 37 CFR 1.85(a). | | | | |
| | Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11)☐ The oath or declaration is object | ed to by the Exam | iner. Note the attached | Office Action or form P | TO-152. | | | |
| Priority under 35 U.S.C. § 119 | | | | | | | |
| 12)☐ Acknowledgment is made of a cl | aim for foreign pri | ority under 35 U.S.C. § | 119(a)-(d) or (f). | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None | a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | | |
| 1. Certified copies of the price | 1. Certified copies of the priority documents have been received. | | | | | | |
| | 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| · | | | | | | | |
| application from the Intern | • | • • • | | | | | |
| * See the attached detailed Office a | action for a list of t | he certified copies not r | eceived. | | | | |
| | · | | | | | | |
| Attachment(s) | | | _ | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Revi | ew (PTO-948) | | ummary (PTO-413))/Mail Date | • | | | |
| 3) Information Disclosure Statement(s) (PTO/SB | | 5) 🔲 Notice of In | formal Patent Application | | | | |
| Paper No(s)/Mail Date 6) Other: | | | | | | | |

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DETAILED ACTION

Current Status

Claims 1-56 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-53 drawn to a process for the hydrogenation and/or asymmetric hydrogenation of imine of formula I, classified in class 585, subclass 513+.

Group 4. Claims 54-56 drawn to a process for the preparation of the compound of formula IV, classified in class 518, subclass 716+.

The inventions of Groups 1-2 are independent and patentably distinct because Group 1-2 are drawn to two different processes for making two different compounds. There is no patentable co-action among the two groups and a reference anticipating one member will not render the other obvious. These two groups are different inventions and require different search strategies.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, a search of the two groups designated above would impose an undue burden upon the examiner, and restriction for examination purposes as indicated is therefor proper.

During a telephone conversation with Patricia Folkins on 11/16/2007, a provisional election was made without traverse to prosecute the invention of Group 1,

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claims 1-53. Applicants are reminded of their right to file divisional applications to the non-elected claims.

Applicants' are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 provide for the method for making an amine from an imine, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a process without any active, positive steps delimiting how this use is actually practiced.

Claim 1 is rejected under 35 U.S.C. 101 because the claimed recitation of a process of making an amine from an imine, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*,

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153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite because the word "includes" renders the claim indefinite.

Because it is not clear what else is included in the catalyst system. Correction is required. See pane 5, line 4.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cobley et al., {US 6,528,687, same as WO 2002008169}.

Cobley et al. disclose applicant's claimed process of making amine from imine in the presence of a base, a ruthenium complex of a chiral diphosphine and a chiral diamine. See abstract and columns 1-8.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Tararov et al., {Phosphines versus phosphinites as ligands in the rhodium catalyzed asymmetric

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hydrogenation of imines a systematic study, Tetrahedron: Asymmetry (1999), 10(20), 4009-4015}.

Tararov et al. disclose applicant's claimed process of making amine from imine.

See abstract.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining

1. Determining the scope and contents of the prior art.

obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cobley et al., {US 6,528,687, same as WO 2002008169}.

Applicants claim a method for producing an amine from an imine in the presence of a base, a ruthenium complex comprising: a diamine, diphosphine ligand or monodentate diphosphine ligand; wherein all the other variables are as defined in the claims.

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Determination of the scope and content of the prior art (M.P.E.P. §2141.01)

Cobley et al. teach applicant's claimed process of making an amine from an imine in the presence of a base, a ruthenium complex of a chiral diphosphine and a chiral diamine. Cobley et al. teach a process wherein the substituent (R³ in formula 10 or 11) on the nitrogen is non-interfering organic group, and the Examiner has interpreted this group to be hydrogen substituted C-C double bond or C-C triple bond. The reaction was conducted in an organic solvent. See abstract and columns 1-8.

Ascertainment of the difference between the prior art and the claims (M.P.E.P...

<u>Ascertainment of the difference between the prior art and the claims (M.P.E.P..</u> §2141.02)

Cobley et al. process for preparing an amine from an imine differs from the instantly claimed process in that applicants' claimed process wherein the three substituents (R², R² and R³) on the nitrogen is in formulas I and II are broader in scope than the three substituents (R², R² and R³) on the nitrogen is in formulas I and II of Cobley et al. Another difference between Applicant claimed invention and the teaching of Cobley et al. is that Applicants claim a base such as DBU, NR₃ and phosphazene while Cobley et al. teach base in general including t-BuOK.

Finding of prima facie obviousness--rational and motivation (M.P.E.P.. §2142-2143)

The instantly claimed process for preparing an amine from an imine would have been suggested to one of ordinary skill because one of ordinary skill wishing to obtain an amine from imine is taught to employ the process of Cobley et al.

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One of ordinary skill in the art would have a reasonable expectation of success in practicing the instant invention by varying the process conditions and catalyst from the teaching of Cobley et al. to arrive at the instantly claimed process for preparing an amine. Said person would have been motivated to practice the teaching of the reference cited because it demonstrates that an amines are useful industrial chemicals. The Examiner notes that varying the substituents, reactants or the additives in a chemical reaction is a well-known chemical practice to optimize the process efficiency of the system and does not constitute a patentable distinction. Moreover, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in art at the time of the invention. Therefore, the instantly claimed invention would therefore have been obvious to one of ordinary skill in the art.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 7,256,311.

The presently claimed process for preparing an amine from an imine is disclosed in US 7,256,311. See claims 1-25 of the US 7,256,311.

Applicants claim a process for preparing an amine from an imine, wherein all the variables are as defined in the claims while US 7,256,311 teaches a process for the hydrogenation or asymmetric hydrogenation of dialkyl, alkylalkenyl and dialkenyl imines of formula (II) to provide amines of formula (III), wherein, (i) R¹ and R² are optionally substituted cyclic, linear or branched alkyl or alkenyl; R³ is a hydrogen atom, a hydroxy radical, optionally substituted C₁ to C₈ cyclic, linear or branched alkyl or alkenyl, optionally substituted aryl; or (ii) R1 is alkyl or alkenyl, R2 is alkyl or alkenyl and the two are linked together or with R³ to form one or more rings; using a catalytic system comprising a base and a ruthenium complex containing (1) a diamine and (2) a diphosphine ligand or monodentate phosphine ligands in hydrogenation and asymmetric hydrogenation processes; wherein all the variables are as defined in the claims. See claims 1-25 of US 7,005,547.

$$\mathbb{R}^{1}$$
 \mathbb{R}^{2} \mathbb{R}^{1} \mathbb{R}^{2} \mathbb{R}^{1} Formula III

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims overlaps substantially with the scope A 111 11 4004

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of claims 1-25 of US 7,256,311, and the process for preparing an amine from an imine in US 7,256,311 encompasses the presently claimed invention. They differ in that US 7,256,311 claims a process wherein R³ is an optionally substituted C¹ to C8 linear or branched alkyl or alkenyl (carbon-carbon double bond) while the present invention claim a process wherein R³ is alkynyl (carbon-carbon triple bond). This difference is not a patentable distinction because the two processes operate under similar reaction conditions. US 7,256,311 teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chukwuma O. Nwaonicha, Ph.D. Patent Examiner

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J. PARSA PRIMARY EXAMINER

FU 1

Yvonne (Bonnie) Eyler Supervisory Patent Examiner, Technology Center 1600